



PATENT
Attorney Docket No. 175931
DHHS Ref. No. E-167-97/2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mitchell et al.

Group Art Unit: 1614

Application No. 09/424,519

Examiner: B. Y. S. Kwon

Filed: March 3, 2000

For: **THE USE OF A NITROXIDE OR A PRODRUG
THEREOF IN THE PROPHYLACTIC AND
THERAPEUTIC TREATMENT OF CANCER**

DECLARATION UNDER 37 C.F.R. § 1.131 OF JAMES B. MITCHELL

Commissioner for Patents
Washington, D.C. 20231

I, James B. Mitchell, hereby declare that:

1. I am a co-inventor identified on all of the subject patent application, the parent International Patent Application No. PCT/US98/10685, which was filed May 27, 1998, the parent U.S. Provisional Patent Application No. 60/047,724, which was filed May 27, 1997.

2. Attached hereto as Exhibit 1 are copies of nine pages from an animal lab notebook dated from prior to May 6, 1997, through July 22, 1997. Pages 1 and 2 demonstrate that the p53 knock-out mice (KO1) that were used in the experiments supporting the present inventive methods were received prior to May 6, 1997 and were placed on Tempol or sugar water shortly thereafter. Page 3 describes background and phenotypic information of the KO1 mice. Page 4 demonstrates a summary of information relating to the experiments performed on the KO1 mice. As evident from page 4, both male (M) and female (F) KO1 mice were either administered Tempol (T) or sugar water (C) on the indicated date of treatment (Tx Date) and sacrificed on the indicated date (Sac Date). The autopsy notes of these mice are found on pages 5-7 of Exhibit 1 (dated from prior to May 6, 1997, through July 14, 1997). Page 8 of Exhibit 1 (dated July 22, 1997) demonstrates a pathology/histotechnology laboratory pathology report of the KO1 mice.


D1

In re Appln. of Mitchell et al.
Application No. 09/424,519

Finally, page 9 demonstrates a graph of the results of the experiments performed on the KO1 mice. As evident from page 9, the percent survival is increased for mice that were treated with Tempol.

3. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,


James B. Mitchell, Ph.D.

Date: 1/16/03

M:\Clients\NIH\131-132\175931 decl131.doc